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\*LIMITED TO MATTERS  
 AND PROCEEDINGS BEFORE  
 FEDERAL COURTS & AGENCIES  
 \*\*REGISTERED PATENT AGENT  
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August 24, 2001

1646

WRITER'S DIRECT NUMBER:  
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Commissioner for Patents  
 Washington, D.C. 20231

Re: U.S. Utility Patent Application  
 Appl. No. 09/839,574; Filed: April 23, 2001  
 For: **Compositions and Methods for *in vivo* Delivery of  
 Polynucleotide-Based Therapeutics**  
 Inventors: Manthorpe *et al.*  
 Our Ref: 1530.0180002/EKS/EJH

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Information Disclosure Statement;
2. Listing of the cited documents on Form PTO-1449 (9 sheets);
3. A copy of each of the forty-five (45) cited documents (AA1, AB1, AC1, AD1, AE1, AF1, AG1, AH1, AI1, AJ1, AK1, AL1, AM1, AN1, AO1, AP1, AR1, AS1, AT1, AA2, AB2, AR2, AS2, AT2, AR3, AS3, AT3, AR4, AS4, AT4, AR5, AS5, AT5, AR6, AS6, AT6, AR7, AS7, AT7, AR8, AS8, AT8, AR9, AS9 and AT9) on Form PTO-1449; and
4. Return Postcard.

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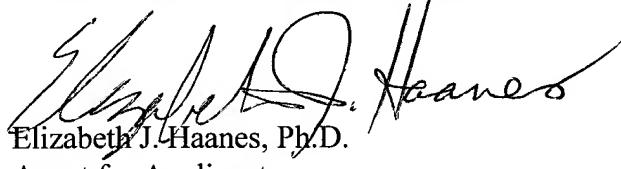
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It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Elizabeth J. Haanes, Ph.D.  
Agent for Applicants  
Registration No. 42,613

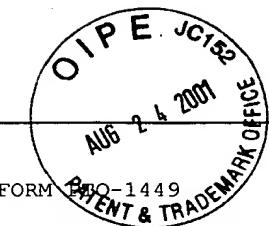
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INFORMATION DISCLOSURE STATEMENT FORM PTO-1449 PATENT & TRADEMARK OFFICE		ATTY. DOCKET NO. 1530.0180002/EKS/EJH	APPLICATION NO. 09/839,574
		APPLICANT Manthorpe et al.	
		FILING DATE 04/23/2001	GROUP 1646

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## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	5,470,568	11/28/1995	Lee	424	78.02	02/13/1992
	AB1	5,580,859	12/03/1996	Felgner et al.	514	44	03/18/1994
	AC1	5,589,466	12/31/1996	Felgner et al.	514	44	01/26/1995
	AD1	5,703,055	12/30/1997	Felgner et al.	514	44	01/26/1994
	AE1	5,855,913	01/05/1999	Hanes et al.	424	489	01/16/1997
	AF1	5,883,103	03/16/1999	Burnside et al.	514	262	06/07/1995
	AG1	5,885,590	03/23/1999	Hunter et al.	424	280.1	01/20/1995
	AH1	5,897,876	04/27/1999	Rudnic et al.	424	455	06/20/1997
	AI1	5,952,004	09/14/1999	Rudnic et al.	424	455	08/28/1995
	AJ1	5,962,428	10/05/1999	Carrano et al.	514	44	09/16/1996
	AK1	5,985,309	11/16/1999	Edwards et al.	424	426	11/17/1997

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 99/26663 A2	06/03/1999	WIPO			Yes No
	AM1	WO 99/64615 A1	12/16/1999	WIPO			Yes No
	AN1	WO 00/40273 A2	07/13/2000	WIPO			Yes No
	AO1	WO 00/40273 A3	07/13/2000	WIPO			Yes No
	AP1	WO 01/09303	02/08/2001	WIPO			Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Adams-Graves et al., "RheothRx (poloxamer 188) injection for the acute painful episode of sickle cell disease: a pilot study," <i>Blood</i> 90:2041-2046, American Society for Hematology, W. B. Saunders Co. (1997).
AS	1	Anwer, K. et al., "Synergistic effect of formulated plasmid and needle-free injection for genetic vaccines," <i>Pharm. Res.</i> 16:889-895, American Association of Pharmaceutical Scientists (June 1999).
AT	1	Baranov, A. et al., "Local and distant transfection of mdx muscle fibers with dystrophin and LacZ genes delivered in vivo by synthetic microspheres," <i>Gene Ther.</i> 6:1406-1414, Stockton Press (Aug 1999).

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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT <small>PATENT &amp; TRADEMARK OFFICE</small>		ATTY. DOCKET NO. 1530.0180002/EKS/EJH	APPLICATION NO. 09/839,574
		APPLICANT Manthorpe et al.	
		FILING DATE 04/23/2001	GROUP 1646

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	5,994,314	11/30/1999	Eljamal et al.	514	44	04/14/1995
	AB	6,214,804 B1	04/10/2001	Felgner et al.	514	44	06/07/1995
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Bertling, W.M. et al., "Use of liposomes, viral capsids, and nanoparticles as DNA carriers," <i>Biotechnol. Appl. Biochem.</i> 13:390-405, Portland Press Limited (1991).
AS	2	Boussif, O. et al., "A versatile vector for gene and oligonucleotide transfer into cells in culture and in vivo: polyethylenimine," <i>Proc. Natl. Acad. Sci. USA</i> 92:7297-7301, National Academy of Sciences (1995).
AT	2	Cho, C.-W. et al., "Improvement of receptor-mediated gene delivery to HepG2 cells using an amphiphilic gelling agent," <i>Biotechnol. Appl. Biochem.</i> 32:21-26, Portland Press Limited (August 2000).

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		APPLICANT Manthorpe et al.	
		FILING DATE 04/23/2001	GROUP 1646

## U.S. PATENT DOCUMENTS

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## FOREIGN PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	3	Doh, S.G. et al., "Spatial-temporal patterns of gene expression in mouse skeletal muscle after injection of lacZ plasmid DNA," <i>Gene Ther.</i> 4:648-663, Stockton Press (1997).
AS	3	Freeman, D.J. and Niven, R.W., "The influence of sodium glycocholate and other additives on the in vivo transfection of plasmid DNA in the lungs," <i>Pharm. Res.</i> 13:202-209, American Association of Pharmaceutical Scientists (1996).
AT	3	Kariko, K. et al., "Phosphate-enhanced transfection of cationic lipid-complexed mRNA and plasmid DNA," <i>Biochim. Biophys. Acta.</i> 1369:320-334, Elsevier Science Ltd. (1998).

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	AL						Yes
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	4	Kichler, A. et al., "Influence of the DNA complexation medium on the transfection efficiency of lipospermine/DNA particles," Gene Ther. 5:855-860, Stockton Press (1998).
AS	4	Lee, R. et al., "Surfactant-induced sealing of electroporated skeletal muscle membranes in vivo," Proc. Natl. Acad. Sci. U.S.A 89:4524-4528, National Academy of Sciences (1992).
AT	4	Lemieux, P. et al., "A Combination of Poloxamers Increases and Prolongs Gene Expression of Plasmid DNA in Skeletal Muscle," Abstracts Presented at the Seventh Meeting of the European Society of Gene Therapy. Munich, Germany, November 26-28 1999.

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Lemieux, P. et al., "A combination of poloxamers increases gene expression of plasmid DNA in skeletal muscle," <i>Gene Ther.</i> 7:986-991, Stockton Press (June 2000).
AS	5	Leong, K.W. et al., "DNA-polycation nanospheres as non-viral gene delivery vehicles," <i>J. Control. Release</i> 53:183-93, Elsevier Science B.V. (1998).
AT	5	Liu, F. et al., "Effect of Non-Ionic Surfactants on the Formation of DNA/Emulsion Complexes and Emulsion-Mediated Gene Transfer," <i>Pharmaceutical Research</i> 13:1642-1646, Plenum Publishing Corporation (1996).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	6	Lunsford, L. et al., "Tissue distribution and persistence in mice of plasmid DNA encapsulated in a PLGA-based microsphere delivery vehicle," <i>J. Drug Target.</i> 8:39-50, Gordon and Breach Publishing Group (November 2000).
AS	6	Mumper, R.J. et al., "Protective interactive noncondensing (PINC) polymers for enhanced plasmid distribution and expression in rat skeletal muscle," <i>J. Control. Release</i> 52:191-203, Elsevier Science B.V. (1998).
AT	6	Mumper, R.J. et al., "Polyvinyl derivatives as novel interactive polymers for controlled gene delivery to muscle," <i>Pharm. Res.</i> 13:701-709, American Association of Pharmaceutical Scientists (1996).

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	AL						Yes
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	AN						Yes
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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	O'Keefe et al., "Poloxamer-188 as an adjunct to primary percutaneous transluminal coronary angioplasty for acute myocardial infarction," Am. J. Cardiol. 78:747-750, Elsevier Science Ltd. (1996).
	AS	7	Orson, F.M. et al., "Genetic immunization with lung-targeting macroaggregated polyethyleneimine-albumin conjugates elicits combined systemic and mucosal immune responses," J. Immunol. 164:6313-6321, American Association of Immunologists (June 2000).
	AT	7	Raczka, E. et al., "The effect of synthetic surfactant Exosurf on gene transfer in mouse lung in vivo," Gene Ther. 5:1333-1339, Stockton Press (1998).

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AR	8	Sawa, T. et al., "Intraluminal water increases expression of plasmid DNA in rat lung," <i>Hum. Gene Ther.</i> 7:933-941, Mary Ann Liebert, Inc. (1996).
AS	8	Shi, N.Y. et al., "Noninvasive gene targeting to the brain," <i>Proc. Natl. Acad. Sci. USA</i> 97:7567-7572, National Academy of Sciences (June 2000).
AT	8	Turunen, M.P. et al., "Efficient adventitial gene delivery to rabbit carotid artery with cationic polymer-plasmid complexes," <i>Gene Ther.</i> 6:6-11, Stockton Press (January 1999).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	9	Wells, D.J. et al., "Evaluation of Plasmid DNA for in Vivo Gene Therapy: Factors Affecting the Number of Transfected Fibers," <i>Journal of Pharmaceutical Sciences</i> 87:763-768, American Chemical Society and American Pharmaceutical Association (1998).
AS	9	Wheeler, C.J. et al., "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung," <i>Proc. Natl. Acad. Sci. USA</i> 93:11454-11459, National Academy of Sciences (1996).
AT	9	Pending Non-Provisional United States Patent Application No. 09/557,907, Horton et al., filed April 21, 2000.

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